

Remarks

Claims 1-28 were previously pending in the subject application. By this Amendment, the applicants have amended claims 1-8, 14, 18, 19, 23-25 and 28 and have withdrawn claims 10-13, 26 and 27 from consideration as being non-elected subject matter due to a restriction requirement. Accordingly, claims 1-9, 14-25 and 28 are before the Examiner for consideration. Favorable consideration of the claims now presented is respectfully requested.

Support for the amendments set forth herein can be found throughout the subject specification, including for example, at page 6, lines 27-30; page 11, lines 1-2 and 13-23; and page 12, lines 13-19. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter, and to expedite prosecution. These amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 2, 3, 5, 8, 9, 18-23, 25 and 28 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office Action indicates that while SEQ ID NOs. 1 and 2 meet the written description provisions, the variants (e.g., hybridizers, mutants, etc.) encompassed by the claims comprise a genus that is inadequately supported by the instant specification. The applicants specifically traverse this grounds for rejection because the specification, as filed, provides ample evidence to establish that the applicants were in possession of the full scope of the invention, as now claimed, at the time of filing.

Please note that the claims have been amended herein to more precisely delineate the claimed subject matter. In particular, the claims have been amended to incorporate language deemed acceptable by the USPTO. For example, with regard to part (b) of claims 2, 5, 8, 19, 23, the USPTO has acknowledged that "specific" hybridization under "highly stringent" conditions yields structurally similar DNAs. Since a person of skill in the art would not expect substantial variation among species encompassed by a genus defined in terms of stringent hybridization, a single species should be sufficient to demonstrate possession of a claimed genus. See Training Materials for the Revised Interim Written Description Guidelines published January 5, 2001, particularly Example 9.

Therefore, the claims have been amended herein to recite "highly stringent" conditions and incorporate specific hybridization conditions into the claims in accordance with the Examiner's suggestion on page 8, paragraph 2 of the outstanding Office Action.

With regard to part (b) of claims 2, 5, 8, 19, 23, and 25, the USPTO has acknowledged that a genus encompassing proteins that are at least 95% identical to a particular disclosed sequence and having a particularly specified activity does not have substantial variation, since all the variants must possess a specific activity (i.e., Na<sup>+</sup>/H<sup>+</sup> antiporter) and must have at least 95% identity to the reference sequence. Thus, since a person of skill in the art would not expect substantial variation among species encompassed by a genus so defined, a single species should be sufficient to demonstrate possession of a claimed genus. See Training Materials for the Revised Interim Written Description Guidelines published January 5, 2001, particularly Example 14.

Therefore, the claims have been amended herein to recite that the number of amino acids that are altered to "20 or less", which would result in sequences having alterations within 5%, considering that SEQ ID NO: 2 has 535 amino acids in total. Consequently, the claimed sequences are now restricted to those encoding proteins that are at least 95% identical.

Claims 18 and 23 have been separately rejected under 35 USC 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey possession of the claimed invention (i.e., a written description rejection). The Office Action indicates that, while the parent plant is defined in terms of DNA carried, the progeny plant lacks specific identifying characteristics such that it would be impossible to determine whether or not a plant of unknown parentage is covered by the claim. To expedite prosecution, the claims have been amended herein to require that the progeny carries the claimed DNA.

The applicants submit that the claims, as amended, are in full compliance with the written description requirement of 35 U.S.C. §112, first paragraph. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 2, 3, 5, 8, 9, 19-23, 25, and 28 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably enable one to make and use the claimed invention. The Office Action acknowledges that

the specification enables DNAs of SEQ ID NO:1 or DNAs encoding proteins of SEQ ID NO.2, but questions the enablement with regard to the claimed variants. The applicants respectfully traverse this grounds for rejection because the skilled artisan could readily, and without undue experimentation, practice the full scope of the claimed invention.

The enablement decision tree set forth in the "Training Materials For Examining Patent Applications With Respect To 35 USC § 112, First Paragraph - Enablement Chemical/Biotechnical Applications" first asks the question: "Does the specification teach how to make and use at least one embodiment encompassed by the claims as a whole without undue experimentation?" A note to the question states that "if there is a working example, the answer to the question cannot be 'No'." Herein, Applicants not only provide ample guidance as to how to make and use embodiments of the claimed invention but also describe a representative species that falls within the scope of the claimed invention (e.g., the protein of SEQ ID NO:2). Accordingly, the answer to the first question is necessarily "YES".

The second question in the enablement decision tree is: "Are the enabled embodiments representative of the full scope of the claim?" As discussed above, the PTO itself has deemed a single disclosed species to be representative of the genus of variants claimed under these circumstances, since a person of skill in the art would not expect substantial variation among species encompassed within the claimed genus because the highly stringent hybridization conditions and the high degree of homology required by the claims result in structurally similar polypeptides. As the applicants disclose a single representative species, the answer to this second question is necessarily "YES".

Thus, following the guidelines of the enablement decision tree, an enablement rejection is not proper under these circumstances. However, the amendments made above in connection to the written description rejections should address any possible concerns the Examiner's concerns.

In sum, the applicants respectfully submit that the claims as amended meet the enablement and written description requirements of 35 USC 112, first paragraph.

Claims 2, 5, 7, 8, 19, 23, and 25, and claims dependent thereon, have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which the applicants regard as the invention. The applicants have amended the claims herein in accordance with the Examiner's helpful suggestions. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-3 and 28 have been rejected under U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Again, the claims have been amended in accordance with the Examiner's helpful suggestion. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 2, 3, 5-9, 14-25, and 28 have been rejected under 35 USC §102(b) as being anticipated by Hiei et al. The applicants respectfully traverse this grounds for rejection because the cited reference does not disclose or suggest the claimed invention.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2<sup>nd</sup> Cir. 1942).

Thus, in order to anticipate a claim, a single reference must disclose each and every element of the claim. In this case, Hiei fails to disclose any relationship between GUS and SEQ ID NOs: 1 and 2, such as is required by the claims as amended herein. Moreover, Hiei fails to disclose a

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transformant cell, transformed plant or offspring or clone thereof transformed with the claimed DNA. Accordingly, claims 2, 3, 5-9, 14-25, and 28 as amended herein are not anticipated by Hiei *et al.*, and the applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 28 has been rejected under 35 U.S.C. §102(b) as being anticipated by Sasaki *et al.* (GenBank Accession No. C91832, 20 April 1998, Applicant's IDS). The applicants respectfully traverse this grounds for rejection.

According to the Office Action, Sasaki *et al.* teach a nucleic acid that is 95% similar to SEQ ID NO.: 1 over a stretch of at least 15 nucleotides. Thus, it is presumed in the Office Action that Sasaki's sequence would hybridize with the DNA of SEQ ID NO:1 under stringent conditions.

As discussed above, in order to anticipate a claim, a single reference must disclose each and every element of the claim. In this case, claim 28 has been amended to require a homology of 96% or more. Accordingly, claim 28 as amended herein is not anticipated by Sasaki *et al.*, and the applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 18 and 23 have been rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiei *et al.* (The Plant Journal, 1994, Vol. 6, No. 2, pages 271-282). The shortcomings of the Hiei *et al.* reference have been discussed above in the context of the rejection under 35 U.S.C. §102. As explained above, Hiei *et al.* do not disclose the claimed subject matter. Nor is there any motivation or suggestion to modify the teachings of Hiei *et al.* to arrive at the claimed subject matter.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, the cited reference does not contain any teaching or suggestion of the claimed invention. It is only the applicants' disclosure that provides such a teaching, and the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a

whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art . . . .” *In re Dow Chemical Co.*, *supra* at 1531. In the reference cited in support of the §103 rejection, one finds neither. Therefore, The applicants respectfully request reconsideration and withdrawal of the rejection set forth under U.S.C. §103(a).

In view of the foregoing remarks and the amendments above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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